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10/552,477

10/31/2006

Manoj Mazhuvancheril Babu

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03/03/2010

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EXAMINER

HOLT, ANDRIAE M

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

03/03/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/552,477 | Applicant(s) BABU ET AL. | |
| | Examiner Andriae M. Holt | Art Unit 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-32 are pending in the application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-12, drawn to an aqueous pharmaceutical composition comprising a) a fluoroquinolone active agent; b) a steroidal or non-steroidal anti-inflammatory agent; c) cyclodextrin; d) an hydroxy acid; e) a co-solubilizer, and f) water and a method of treating a bacterial infection of an eye.

Group II, claim(s) 13-24, drawn to a pharmaceutical formulation comprising a) a fluoroquinolone active agent; b) a steroidal or non-steroidal anti-inflammatory agent; c) cyclodextrin; and d) an hydroxy acid.

Group III, claim(s) 25-28, drawn to a method of topically applying a pharmaceutical composition containing an active compound to the eye.

Group IV, claim(s) 29-32, drawn to a topical pharmaceutical composition containing an active compound used to topically apply said active compound to the eye of a subject in need thereof.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Chandavarkar et al. (WO 02/39993) disclose a combination drug that comprises i) an anti-inflammatory agent which is a corticosteroid (steroidal anti-inflammatory agent); ii) an anti-infective agent selected from the group comprising derivatives of quinolone (fluoroquinolone

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active agent); iii) a complexation enhancing polymer; iv) a solubilizer exhibiting an inclusion phenomenon (cyclodextrin), along with pharmaceutically acceptable excipients with a suitable carrier system (water) (Abstract). Chandavarkar et al. discloses the combination drug when incorporated in a carrier system of water or gel is suitable for ocular treatment. In addition, Applicant has claimed different inventions. The invention of Group II, a composition, does not comprise a co-solubilizer and water. The invention of Group IV, a composition, comprises an active compound and 5% by weight of a soluble polymer. This active compound can be any compound that can be topically applied to the eye. The composition of Group IV does not contain any of the components of the compounds of claim 1 or claim 13. Therefore, a feature found in the prior art and different inventions cannot be considered to be a special technical feature.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Claim 1 recites the following species of “steroidal or non-steroidal anti-inflammatory compound”.

Claims 9 and 22 recite the following species of “fluoroquinolone active agent”:
Gatifloxacin, moxifloxacin, sitafloxacin ...ciprofloxacin.

Claims 10 and 23 recite the following species of “steroidal compound”:
Cortisone, hydrocortisone, deoxycorticosterone ...fludrocortisone.

Claims 11 and 24 recite the following species of “non-steroidal anti-inflammatory compound”:
Aspirin, diclofenac, indomethacin....S-2474.

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Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is required to elect a single species for fluoroquinolone active agent, steroidal or non-steroidal compound of claim 1. If Applicant elects steroidal compound, a compound of claims 10 or 23 should be elected. If Applicant elects non-steroidal compound, a compound of claims 11 or 24 should be elected. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim 2 recites the species of "steroidal or non-steroidal anti-inflammatory compound" " used in the invention of Group I.

Claim 9 recites various species of "fluoroquinolone active agent" used in the invention of Group I.

Claim 10 recites various species of "steroidal compound " used in the invention of Group I.

Claim 11 recites various species of "non-steroidal anti-inflammatory compound" used in the invention of Group I.

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Claim 22 recites various species of "fluoroquinolone active agent " used in the invention of Group II.

Claim 23 recites various species of "steroidal compound " used in the invention of Group II.

Claim 24 recites various species of "non-steroidal anti-inflammatory compound " used in the invention of Group II.

The following claim(s) are generic: 1 and 13

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Pursuant to PCT Rule 13.2 and PCT Administrative Instructions, Annex B, Part 1 (f)(I)(B)(2), the species are not art recognized equivalents.

A telephone call was made to Bryan Davidson on November 24, 2009 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does

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not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Applicant is reminded in order for the restriction requirement to be complete an election of a single invention from Groups I-IV should be made and an election of a single species from the following species: fluoroquinolone active agent such as ciprofloxacin; steroidal compound such as dexamethasone; and non-steroidal compound such as aspirin.

CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is (571)272-9328. The examiner can normally be reached on 7:00 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richter Johann can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andriae M. Holt
Patent Examiner
Art Unit 1616

/John Pak/
Primary Examiner, Art Unit 1616